and effective September 16, 1995, which is incorporated by reference in 14 CFR 71.1. The Class D airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26. 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

in consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 16, 1995, is amended as follows:

Paragraph 5000 Class D Airspace

* * * * *

ANM WA D Vancouver, WA

Vancouver, Pearson Airpark, WA
(Lat. 45°37′14″N, long. 122°39′30″W)
Portland International Airport, OR
(Lat 45°35′19″N, long. 122°35′51″W)

That airspace extending upward from the surface to but not including 1,100 feet MSL in an area bounded by a line beginning at the point where the 019° bearing from Pearson Airpark intersects the 5-mile arc from Portland International Airport extending southeast to a point 1½, miles east of Pearson Airpark on the extended centerline of Runway 8/26, and thence south to the north shore of the Columbia River, thence west via the north shore of the Columbia River to the 5-mile arc from Portland International Airport and thence clockwise via the 5-mile arc to point of beginning.

* * * * *

Issued in Seattle, Washington, on October 26, 1995.

Richard E. Prang,

Acting Assistant Manager, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 95–27830 Filed 11–8–95; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 945

Hawaiian Islands Humpback Whale National Marine Sanctuary

AGENCY: Office of Ocean and Coastal Resource Management (OCRM), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Notice of public hearings.

SUMMARY: The OCRM is announcing the dates and places of public hearings on a Draft Environmental Impact Statement/Management Plan and proposed regulations for the Hawaiian Islands Humpback Whale National Marine Sanctuary.

DATES: For the dates of the hearings see the Supplementary Information section.

ADDRESSES: For the locations of the hearing see the Supplementary Information section.

FOR FURTHER INFORMATION CONTACT: Allen Tom, On-site Project Specialist, at (808) 879–2818 (Maui), (808) 541–3184 (Oahu) or (800) 831–4888 (toll-free interisland). Copies of the DEIS/MP and Proposed Rules are available upon request to the Hawaiian Islands Humpback Whale National Marine Sanctuary, 726 South Kihei Road, Kihei, HI 96753.

SUPPLEMENTARY INFORMATION: The Hawaiian Islands Humpback Whale National Marine Sanctuary was designated by law on November 4, 1992 (Subtitle C, Title II, Pub. L. 101–587 (Oceans Act of 1992)). The primary purpose of the designation is to protect humpback whales and their habitat in the Hawaiian Islands. A notice of the availability of the Draft Environmental Impact Statement/Management Plan (DEIS/MP), the proposed regulations, and a summary of the management plan were published in the Federal Register on September 15, 1995 (60 FR 48000).

OCRM will hold public hearings on the DEIS/MP and Proposed Regulations. The purpose of the public hearings is to receive oral testimony from the public on the DEIS/MP and Proposed Rules. The comments expressed at these hearings, as well as written comments received on the DEIS/MP and Proposed Rules, will be considered in the preparation of the Final Environmental Impact Statement/Management Plan (FEIS/MP) and Rules. Written comments may also be submitted at these public meetings or mailed to the Hawaiian Islands Humpback Whale National Marine Sanctuary, 726 South Kihei Road, Kihei, HI. The period to receive written comments ends on December 15, 1995.

Date, Time and Place of Public Hearings:

November 27, 7:00 PM: Hawaii County Council Room, 25 Aupuni Street, Hilo, Hawaii

November 28, 7:00 PM: Kealakehe Elementary School, 74–511 Kealakaa Street, Kailua-Kona, Hawaii

November 29, 7:00 PM: Kaunoa Senior Center Cafeteria, 401 Alakapa Place, Pa'ia, Maui

November 30, 7:00 PM: Tokai University Auditorium, 2241 Kapiolani Blvd., Honolulu, Oahu

December 4, 7:00 PM: Lanai School and Public Library, 6th and Fraiser Ave, Lanai City, Lanai

December 5, 7:00 PM: Molokai Yacht Club, Hio Place, Kauanakakai, Molokai

December 6, 7:00 PM: Wilcox Elementary School Cafeteria, 4319 Hardy Street, Lihue, Kauai

Public Participation: The hearings will be open to public participation. Seats will be available on a first-come first-served basis. There will be a sign up sheet at each location for anyone wishing to give testimony. Individual speakers and organizations will be given a 3 minute time limit to present their testimony.

(Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: November 6, 1995.

David L. Evans,

Acting Deputy Assistant Administrator for Ocean Services and Coastal Zone Management.

[FR Doc. 95–27911 Filed 11–8–95; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101, 131, and 133

[Docket Nos. 95P–0125, 95P–0250, 95P–0261, and 95P–0293]

Lowfat and Skim Milk Products, Lowfat and Nonfat Yogurt Products, Lowfat Cottage Cheese: Proposed Revocation of Standards of Identity; Food Labeling, Nutrient Content Claims for Fat, Fatty Acids and Cholesterol Content of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to remove the standards of identity for sweetened condensed skimmed milk, lowfat milk, skim (nonfat) milk, acidified lowfat milk, acidified skim (nonfat) milk, cultured lowfat milk, cultured skim (nonfat) milk, sour half-and-half, acidified sour half-and-half, lowfat yogurt, nonfat yogurt, and lowfat cottage cheese, based in part, on petitions filed jointly by the Milk Industry Foundation (MIF) and the Center for Science in the Public Interest (CSPI). FDA also is proposing to remove the standards of identity for evaporated skimmed milk and lowfat dry milk based on a petition filed by the American Dairy Products Institute (ADPI). Removal of these food standards of identity would permit the products covered by these regulations to be manufactured and labeled in accordance with the general definition and standard of identity (the general standard) in the regulations for foods named by use of a nutrient content claim and a standardized term. These products would then be named in a manner that is consistent with the agency's definitions of the terms ''lowfat'' and ''nonfat'' established in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). This action will provide for consistency in the nomenclature and labeling of these nutritionally modified milk products and other foods bearing ''lowfat'' and ''nonfat'' claims and will promote honesty and fair dealing in the interest of consumers.

The agency also is proposing to amend the nutrient content claims regulations for fat, fatty acids, and cholesterol content to provide for ''skim'' as a synonym for ''nonfat'' when used in labeling milk products.

This action also is a part of the agency's ongoing review of existing regulations under President Clinton's Regulatory Reinvention Initiative.

DATES: Comments by January 23, 1996. FDA proposes that any final rule that may issue based on this proposal, unless stayed by the filing of proper objections, become effective January 1, 1998. Compliance may begin on the date of publication of the final rule in the Federal Register.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nannie H. Rainey, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION:

I. Background

A. Regulatory History

One of the main purposes of the 1990 amendments (Pub. L. 101–535) which amended the Federal Food, Drug, and Cosmetic Act (the act), was to establish the circumstances in which claims that describe the nutrient content of food could be made. In response to the mandates of the 1990 amendments, FDA established definitions for specific nutrient content claims in part 101 (21 CFR part 101) together with principles for their use (58 FR 2302, January 6, 1993). In addition, at the same time, FDA published a final rule (58 FR 2302 at 2431), that established the general standard in § 130.10 (21 CFR 130.10) for foods named by use of a nutrient content claim defined in part 101, such as ''nonfat,'' ''lowfat,'' ''reduced fat,'' ''light,'' or ''reduced calorie,'' in conjunction with a traditional standardized term, for example, ''sour cream.''

As FDA noted in that final rule, certain standards of identity for dairy products already incorporate terms such as ''nonfat,'' ''light,'' and ''lowfat'' in the names of the foods, including the standards for lowfat dry milk (§ 131.123 (21 CFR 131.123)), nonfat dry milk (§ 131.125 (21 CFR 131.125)), nonfat dry milk fortified with vitamins A and D (§ 131.127 (21 CFR 131.127)), lowfat milk (§ 131.135 (21 CFR 131.135)), acidified lowfat milk (§ 131.136 (21 CFR 131.136), cultured lowfat milk (§ 131.138 (21 CFR 131.138)), light cream (§ 131.155 (21 CFR 131.155)), lowfat yogurt (§ 131.203 (21 CFR 131.203)), nonfat yogurt (§ 131.206 (21 CFR 131.206)), and lowfat cottage cheese (§ 133.131 (21 CFR 133.131)). In addition, there are standards for skim milk products that provide for use of the synonym ''nonfat'' in place of the term ''skim'' in the names of these foods. For example, skim milk (§ 131.143 (21 CFR 131.143)), acidified skim milk (§ 131.144 (21 CFR 131.144)), and cultured skim milk (§ 131.146 (21 CFR 131.146)) may be labeled as ''nonfat milk,'' ''acidified nonfat milk,'' and ''cultured nonfat milk,'' respectively. Some of the names in these standards are inconsistent with the definitions for the corresponding nutrient content claims established under the 1990 amendments.

Under section 403(r)(1)(A) of the act (21 U.S.C. 343(r)(1)(A)), a food is misbranded if it bears a claim that characterizes the level of any nutrient unless the claim is made using terms defined by the regulations of the Secretary of Health and Human Services. Section 403(r)(5)(C) of the act provides an exemption from this requirement, however, for nutrient content claims that are part of the name of a food that is defined by a standard of identity that was issued before enactment of the 1990 amendments. According to the legislative history, this exemption was included in the law because Congress recognized the possibility that nomenclature and nutrient content claims requirements in preexisting standards of identity might conflict with the nutrient content claim definitions adopted under the 1990 amendments (H. Rept. 101–538, 101st Cong., 2d sess. 22, June 13, 1990). The legislative history went on to state that to the extent that those standards provide requirements that are different from the definitions in the regulations issued by FDA under the 1990 amendments, one basic purpose of the 1990 amendments will be partially undermined (id.). However, the legislative history affirmed that the Secretary of Health and Human Services (and, by delegation, FDA) has the authority to correct this problem by amending the standards of identity to conform with the regulations issued under section 403(r) of the act (id.).

The agency stated in the final rule establishing the general standard (58 FR 2431 at 2444) that, at a later date, it would consider amending the existing standards of identity for foods that use nutrient content claims in their names to make the content requirements for these foods consistent with the claims definitions it adopted. Alternatively, the agency stated that it could delete some of the standards and allow the foods defined by these standards to be named

using a nutrient content claim with a standardized term in accordance with the general standard (§ 130.10). The proposed actions set out below are intended, in part, to implement the latter option.

B. MIF and CSPI Petitions

This proposal also responds to two petitions filed by MIF and CSPI, dated May 10, 1995 (Docket No. 95P–0125) and August 2, 1995 (Docket No. 95P–0250). The May 10, 1995, petition, requests that the agency revoke the standard of identity for lowfat milk in § 131.135 and the standard of identity for skim milk in § 131.143 and to regulate these products under the general standard in § 130.10. The August 2, 1995, petition, which references the May 10, 1995, petition, requests that the agency revoke the standards of identity for 10 additional products (i.e., sweetened condensed skimmed milk (§ 131.122 (21 CFR 131.122)), acidified lowfat milk (§ 131.136), cultured lowfat milk (§ 131.138), acidified skim (or nonfat) milk (§ 131.144), cultured skim (or nonfat) milk (§ 131.146), sour half-and-half § 131.185 (21 CFR 131.185)), acidified sour half-and-half § 131.187 (21 CFR 131.187)), lowfat yogurt (§ 131.203), nonfat yogurt (§ 131.206), and lowfat cottage cheese (§ 133.131)) that include nutrient content claims in their names. The petitioners stated that the purpose of the petitions is to promote consistency in the use of nutrient content claims concerning fat on food labels.

To provide for the continued use of the term ''skim'' in the labeling of these skim milk products if FDA were to revoke the standards for these foods as requested, MIF and CSPI submitted a third petition, dated August 2, 1995, which requests that the agency amend the nutrient content claims regulations in § 101.62 to permit the use of the term ''skim'' as a synonym for the term ''nonfat.'' That petition was filed under Docket No. 95P–0293.

C. Niagara County Healthy Heart Program Petition

FDA also received a petition from the Niagara County Healthy Heart Program (Docket No. 93P–0089) that requests that the agency amend the standards of identity for lowfat milk (§ 131.135), acidified lowfat milk (§ 131.136), and cultured lowfat milk (§ 131.138) by deleting the two upper-levels for milkfat content in these foods. These standards currently provide for the following fat levels: ½, 1, 1½, or 2 percent milkfat. The petitioner stated that milkfat levels of 1½ or 2 percent provided by these standards result in products that contain more than 3 grams (g) fat per serving and that, thus, are inconsistent with the agency's definition of ''low fat.'' In addition, the petitioner claimed that these exceptions in the standards of identity have the potential to confuse consumers and therefore should be removed.

The agency notes that if the standards of identity for the lowfat milk products are revoked, as proposed below, the need to remove the upper-limits for milkfat (1½ and 2 percent) in these standards will be rendered moot. However, if the comments do not support revocation of the lowfat milk standards, the agency will consider alternative actions such as those suggested by the petitioner as a means of correcting the inconsistency between the standards in §§ 131.135, 131.136, and 131.138, and the nutrient content claims regulations in § 101.62((b)(2) regarding the use of the term ''low fat'' on food labels.

D. ADPI Petitions

This proposal also responds to two petitions filed by ADPI. One ADPI petition, filed on August 11, 1995 (Docket No. 95P–0261), requests that the agency revoke the standards of identity for evaporated skimmed milk in (§ 131.132 (21 CFR 131.132)) and lowfat dry milk in § 131.123 and amend the standard of identity for dry cream in (§ 131.149 (21 CFR 131.149)) by removing the reference to § 131.135 (the lowfat milk standard, which is being proposed for revocation). According to the petitioner, their suggested change would remove the lower-fat evaporated milk and dry milk standards that contain product specifications that potentially conflict with approved nutrient content claims applicable to foods in general. The petition would also amend the dry cream standard so as to bring it into conformity with the other suggested changes in the milk product standards.

The other ADPI petition (Docket No. 95P–0293, dated August 10, 1995) requests that the agency provide for use of the term ''skim'' as a synonym for ''nonfat'' in § 101.62. ADPI stated that providing for this term would allow use of the familiar term ''skim'' in the name of the lower fat evaporated milk product if the existing standard in § 131.132 is revoked, and this product is manufactured and labeled in conformance with the general definition and standard of identity in § 130.10.

E. Regulatory Reinvention Initiative—Review of Regulations

In addition, this proposal is a part of a larger agency project being undertaken in response to President Clinton's memorandum of March 4, 1995, to heads of departments and agencies, entitled ''Regulatory Reinvention Initiative'' (Ref. 1). This memorandum, among other things, directs departments and agencies to do a page-by-page review of regulations and to eliminate or revise those that are outdated or otherwise in need of reform. The review of the standards of identity for dairy products has revealed that a number of the products that are defined by individual standards in parts 131 and 133 (21 CFR parts 131 and 133) could be more appropriately covered by the general standard in § 130.10. Thus, the agency is proposing to remove those standards cited by the MIF, CSPI, and ADPI that are inconsistent with food labeling policy established under the 1990 amendments and that are unnecessary in light of the general standard in § 130.10.

II. Grounds for the Petitions

A. Removal of Standards

The petitioners pointed out that the regulations that FDA promulgated in response to the 1990 amendments defined ''nonfat'' and ''low fat'' in ways that are in conflict with the standards of identity for certain dairy products, e.g., skim (nonfat) milk and lowfat milk products. The nutrient content claims regulations (§ 101.62(b)(1)(i)) require that to qualify to bear the term ''nonfat,'' a food must have less than 0.5 g of fat per reference amount customarily consumed. Conversely, the standards of identity for skim milk and the related cultured and acidified skim milk products in §§ 131.143(a), 131.144(a), and 131.146(a), for example, allow these ''nonfat'' milk products to have up to 0.5 percent milkfat, which translates to 1.2 g of fat per 8 fluid ounce serving, that is, per reference amount customarily consumed. Similarly, whereas ''low fat'' foods (§ 101.62(b)(2)(i)(A)) generally must have 3 g or less of fat per reference amount customarily consumed, the standards for ''lowfat'' milk products in §§ 131.135(a), 131.136(a), and 131.138(a), for example, allow these foods to contain as much as 2 percent milkfat, or 5 g of fat per reference amount customarily consumed (up to 60 percent more than is permitted under the definition for the claim).

Thus, the petitioners stated, if a term such as ''low fat'' has one meaning when applied to foods in general and a

different meaning when applied to a widely-consumed staple food such as milk, the result might well be confusion in the minds of many consumers as to the significance of the term. They further noted that the Institute of Medicine, in ''Nutrition Labeling: Issues and Directions for the 1990's,'' p. 251, 1990, stated that ''the message conveyed by quantitative descriptors should be consistent, clear, and reliable * * * [L]ow sodium, for example, should have the same meaning, whether it is applied to soup, frozen peas, or meat.''

MIF and CSPI urged FDA to repeal the standards of identity for lowfat milk, skim milk, and certain related dairy products and to make the use of nutrient content claims for fat in the names of these dairy products consistent with the use of nutrient content claims for fat on other foods. The petitioners asserted that this action would enhance the public health because it would eliminate consumer confusion about the significance of these claims and would facilitate comparisons between these dairy products and other foods.

In further support of their petitions, ADPI, MIF, and CSPI pointed to the agency's expressed intention to establish consistency in nutrient content claims as evidenced by its rejection of comments urging it to define ''low fat'' differently for different foods. The petitioners noted that in the proposed rule to establish definitions for nutrient content claims (56 FR 60478 at 60487 and 60488, November 27, 1991), the agency explained:

> The use of different criteria for different food categories has several disadvantages that affect both consumers and the food industry. When different criteria are used for different categories of foods, consumers cannot use the nutrient content claims to compare products across categories and will likely find it difficult to use the descriptor in substituting one food for another in their diets. * * * Furthermore, by having different criteria for different food categories, it would be possible that some foods that did not qualify to use the descriptor would have a lower fat content than foods in other categories that did qualify. This situation would contribute to consumer confusion and misunderstanding.

The petitioners claimed that this reasoning, which led FDA to adopt uniform definitions for nutrient content claims, should lead the agency to revoke the standards of identity for lower-fat fluid milk and yogurt products. These standards establish criteria for the use of the terms ''lowfat'' and ''nonfat'' in milk product labeling that are inconsistent with the criteria applicable to the labeling of other foods. Consequently, according to the petitioners, the regulations currently contain precisely what FDA has determined to avoid: Different definitions of ''low fat'' for different foods.

The petitioners cited the legislative history of the 1990 amendments as indicating that Congress anticipated that FDA would take action to make the nutrient content claims in standards of identity consistent with those in the regulations established under the 1990 amendments. They also referred to the agency's recognition that it may be appropriate to revoke the standards of identity containing nutrient content claims, such as ''lowfat milk'' and ''skim (nonfat) milk,'' and to subject these foods to the same regulations as other foods (58 FR 2431 at 2444).

The petitioners noted that if the agency were to eliminate the standards of identity for ''lowfat milk'' and ''skim milk'' products, these lower-fat milk products would be labeled according to the general standard in § 130.10. They would be named by a nutrient content claim defined by regulation (such as ''nonfat,'' ''fat free,'' ''low fat,'' or ''reduced fat'') in conjunction with the standardized name for whole milk (i.e., ''milk'') in § 131.110(e)(21 CFR 131.110(e)).

MIF and CSPI also stated that revocation of the standards of identity for sour half-and-half and acidified sour half-and-half would advance Congress's goal of making fat content claims clear and consistent. They claimed that the sour half-and-half products and the counterpart full-fat sour cream products are equivalent in every way except for fat content, and except for the fact that the lower-fat sour cream product names do not include the term ''sour cream.'' They contended that because processors are required to use the standardized name, e.g., ''sour half-and-half,'' ''cultured sour half-and-half,'' or ''acidified sour half-and-half,'' as appropriate, the relationship between these products and their full-fat counterparts, ''sour cream,'' ''cultured sour cream,'' or ''acidified sour cream,'' is obfuscated. Therefore, the petitioners asked that the standards for the sour half-and-half products be revoked.

B. Other Issues

The petitioners stated that two issues needed to be addressed for the revocation of the standards for ''lowfat milk'' and ''skim milk'' to result in labels for the products that can be easily understood by consumers.

The petitioners maintained that most products currently labeled as ''nonfat milk'' would be eligible to retain that name under the general standard because nonfat milk contains less than 0.5 g of fat per serving, in accordance with the definition of the term ''nonfat'' in § 101.62(b)(1)(i). However, the petitioners noted that these products could not be called ''skim milk'' under the general standard because the fat content claims regulations in § 101.62 do not authorize the use of the term ''skim.'' They stated that a significant number of processors presently use the nomenclature ''skim milk,'' and that ''skim'' is the term by which many consumers distinguish between nonfat milk and all other forms of milk. The loss of authority to use this traditional and widely recognized name would thus be extremely disruptive. MIF stated that in view of widespread consumer reliance on the name ''skim milk,'' it regards the approval of the descriptor ''skim'' (as a synonym for ''nonfat'') as essential to its continuing support of the revocation of the skim milk standard.

MIF and CSPI also requested that the agency revoke the standard of identity for sweetened condensed skimmed milk (§ 131.122). The petitioners stated that if the agency provides for the synonym ''skim'' in § 101.62, sweetened condensed skimmed milk could be manufactured and labeled under § 130.10 and could be named using the term ''skim'' in a manner that is consistent with other nonfat milk products.

The second issue to be resolved, according to the petitioners, concerns declaration of the percentage of milkfat in the name of the food. The petitioners suggested that they expected the authority to state the milkfat percentage before the name on product labels to continue under the general standard because section 3(b)(1)(A)(iv) of the 1990 amendments dictates that the regulations ''shall permit statements describing the amount and percentage of nutrients in food which are not misleading and are consistent with the terms defined'' under the act. The petitioners pointed out that the general nutrient content claims regulations in § 101.13(i) implement this provision by providing that:

> * * * the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if: (1) The use of the statement on the food implicitly characterizes the level of the nutrient in the food and is consistent with a definition for a claim * * * or (3) The statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect * * *.

MIF claimed that although the term ''implicitly characterizes'' is somewhat ambiguous, it is clear that a percentage figure can be used if it is consistent with the appropriate nutrient content claim (e.g., ''2% reduced fat''; ''1% lowfat'').

MIF stated that it views the indication of the milkfat percentage before the name of the product as an indispensable aspect of lower-fat milk labeling because consumers have come to rely so heavily on these numbers to differentiate between milk products. MIF further stated that it would not be proposing the revocation of the lower-fat milk standards if it believed that such an action would affect milk processors' ability to state the milkfat percentage in the customary manner.

The petitioners also discussed the nutritional aspect of deleting the lower-fat milk, sour cream, and cottage cheese products standards of identity, stating that this aspect of the proposed action would not require additional action. They claimed that the only distinction of note between the milk standard and the lower-fat dairy product standards (e.g., lowfat milk and skim milk products), in relation to nutritional content, is that vitamin A fortification to 10 percent of the daily value (DV) is optional under the milk standard but mandatory under the lower-fat milk standards. The petitioners stated that, even if the skim milk and lowfat milk product standards were revoked, vitamin A fortification of these products to 10 percent of the DV would remain mandatory under the general standard.

The petitioners noted that because vitamin A is fat soluble, the process of removing fat from milk unavoidably removes some vitamin A. As a result, all commonly marketed lower-fat fluid milk products would be required to have at least some added vitamin A in order to meet the general standard's requirement that they not be nutritionally inferior to milk (§ 130.10(b)). Moreover, they noted, the milk standard in § 131.110(b)(1) states that if vitamin A is added, it must be added to the 10 percent DV level. Consequently, the petitioners concluded, lower-fat milk products, labeled according to the general standard, would have to be vitamin A fortified up to 10 percent of the DV. They concluded that elimination of the lower-fat milk product standards would have no practical effect on the nutritional benefit of these products.

ADPI maintained that revocation of the standards for evaporated skimmed milk and lowfat dry milk will not result in inferior dairy products because these foods are produced by removal of water from dairy products or are mixtures of other dairy products where water has been removed to some extent. ADPI further stated that besides water, the other key variable in evaporated milk and dry milk is fat. By revoking the standards for evaporated skimmed milk and lowfat dry milk, ADPI concluded that the amount of fat present in the products would be communicated through the use of terms (i.e., nutrient content claims) that would be consistent with the same terms applied to other foods. The remaining nutritional attributes of these foods would remain unchanged.

III. Proposed Actions

A. Removal of Standards

FDA agrees with the petitioners that the requested changes are consistent with the agency's stated intent to have consistent definitions across food categories for nutrient content claims. Accordingly, FDA is proposing to repeal the standards of identity for the lower-fat milk, sweetened condensed milk, evaporated milk, dry milk, sour cream (i.e., sour half-and-half or acidified sour half-and-half), and yogurt products, in §§ 131.122, 131.123, 131.132, 131.135, 131.136, 131.138, 131.143 131.144, 131.146, 131.185, 131.187, 131.203, and 131.206, and lowfat cottage cheese in § 133.131 that include nutrient content claims in their names. Repeal of the standards of identity for the lower-fat dairy products would allow these foods to bear the nutrient content claims ''reduced fat,'' ''lowfat,'' or ''nonfat'' in conjunction with the standardized term ''milk,'' ''sweetened condensed milk,'' ''evaporated milk,'' ''dry milk,'' ''sour cream,'' or ''yogurt'' provided that they comply with the general standard in § 130.10. This standard in turn would require that all such products bearing these nutrient content claims comply with the definitions established for the claims in § 101.62. Thus, consumers would be presented with information on the fat content of the modified milk, sour cream, and yogurt products that is consistent with that on other foods and that will enable them to select much more readily those products that will provide, in the case of ''low fat'' foods, 3 g or less of fat per reference amount customarily consumed, or, in the case of ''nonfat'' or ''fat free'' foods, those products that contain less than 0.5 g of fat per reference amount and per labeled serving, than they are able to do under the existing standards.

MIF and CSPI suggested that milk products that are currently labeled as ''2 percent lowfat milk'' or ''1.5 percent lowfat milk,'' and which would not be entitled to bear that name after the standard of identity for lowfat milk is removed, could be labeled as ''2 percent reduced fat milk'' or ''1.5 percent reduced fat milk.'' The agency agrees that a declaration of the percentage of fat is permitted under the nutrient content claims regulations in § 101.13(i). It also agrees that continuing the percentage fat declaration as part of the name would assist consumers in recognizing these milk and yogurt products when the nutrient content claim in the names of these foods is changed from ''lowfat'' to ''reduced fat'' under the general standard (i.e, ''reduced fat milk, 2 percent milkfat,'' or ''reduced fat milk, 2 percent fat''). The agency points out that if it adopts this proposed action, unlike under the existing standards, e.g., in §§ 131.135 and 131.143, which provide that the name include a declaration of the percentage of milkfat, the percentage fat declaration in the name under § 130.10 will be on a total fat basis (milkfat and any fat from added optional ingredients).

ADPI and MIF requested that FDA provide for the continued use of the name ''skim milk'' as an alternative to ''nonfat milk'' after the standards of identity for skim milk products are repealed. They pointed out that the regulations in § 101.62(b) do not provide for the use of ''skim'' as a synonym for ''nonfat'' or ''fat free.'' Thus, the name ''skim milk'' would not be available to producers of skim milk when that product is made under the general standard. ADPI also requested that the term ''skim'' be provided as a synonym for ''nonfat,'' so that the lower-fat evaporated milk product can be labeled in a manner that is consistent with the labeling of other lower-fat fluid milk products.

The agency has considered these requests and is proposing to amend the regulations pertaining to nutrient content claims for fat in § 101.62(b)(1) to include ''skim'' as a synonym for ''nonfat'' in characterizing the level of fat in modified milk products. FDA notes that several standards in part 131 for skim milk products (i.e., skim milk, acidified skim milk, and cultured skim milk in §§ 131.143, 131.144, and 131.146) currently provide for the use of either ''nonfat'' or ''skim'' (or ''skimmed'' in the case of sweetened condensed milk and evaporated milk) in the names of these products. Based on their history of use in dairy product nomenclature, the agency tentatively concludes that consumers understand the name ''skim milk'' to mean the same as ''nonfat milk''. Thus, the agency is proposing under sections 403(r) and 701(a) of the act (21 U.S.C. 371(a)) to include the term ''skim,'' when used to describe milk products, as a synonym for ''nonfat'' in § 101.62(b)(1), as set forth below.

FDA notes that in the absence of a specific standard of identity for the

lower-fat sweetened condensed milk product or evaporated milk product, manufacturers will be provided greater flexibility in selecting the fat levels for these foods when they are made under the general standard. As in the case of the other lower-fat milk and yogurt products, the nutrient content claims used in the naming these foods under § 130.10 will be consistent with those used in the labeling of other foods, thereby decreasing the potential for consumer confusion as to the meaning of these nutrient content claims on food labels.

FDA also is proposing to remove the standard of identity for lowfat cottage cheese in § 133.131. The petitioners stated that virtually all lowfat cottage cheese on the market has less than 3 g of fat per the reference amount customarily consumed of 110 g. If so, this food could continue to be labeled as ''lowfat cottage cheese'' under the general standard. The agency notes that the standard of identity for lowfat cottage cheese in § 133.131(b)(2) requires that the percentage of milkfat in the food be declared as part of the name of the food. Thus, if § 133.131 is removed, there will be no provision requiring percentage declaration of milkfat content in conjunction with the name of this food. However, because the name of the food includes a nutrient content claim, a declaration of the amount of fat per reference amount customarily consumed will appear in the nutrition facts statement on the label. Thus, consumers will continue to have access to information on the fat content of the lowfat cottage cheese that can be used in making purchasing decisions. On the other hand, manufacturers may continue to declare fat content as part of the name of the food as has been suggested by the petitioners for lowfat milk products.

The agency notes that standards of identity for two cream products contain the term ''light'' in the names of the foods, light cream in § 131.155 and light whipping cream in § 131.157 (21 CFR 131.157). FDA is not proposing to change these standards at this time. The agency tentatively concludes that no change is necessary in the names of these foods because of their long history of use, since 1940. These names connote a difference in the texture of these products compared to the higher fat cream product defined in 21 CFR 131.150, heavy cream. In addition, light cream, which contains not less than 18 percent but less than 30 percent milkfat is often labeled by one of its alternative standardized names, as ''table cream'' or ''coffee cream.'' Light whipping cream, which contains not less than 30 percent but less than 36 percent milkfat, is distinguished from heavy whipping cream, which contains 30 percent or more of milkfat, not only by its lower fat content but by its lighter, less dense texture on whipping. The agency requests comments on the appropriateness of these names and on whether consumers find the use of the term ''light'' in the names of these foods to be misleading. If comments demonstrate that amendment of these regulations is necessary, such action will be the subject of a later rulemaking.

As noted by ADPI, the standard of identity for dry cream (§ 131.149) provides that the food is obtained by removal of water only from pasteurized milk or cream or a mixture thereof, which may have been homogenized. The standard also provides that dry cream may be obtained by blending dry milks as defined in §§ 131.123(a), 131.125(a), and 131.147(a) with dry cream, as appropriate, provided that the resulting product is equivalent in composition to that obtained by the method described in the preceding sentence. Because this proposal would remove the standard of identity for lowfat dry milk in § 131.123, ADPI requests that the dry cream standard be amended to delete that reference. The agency also recognizes the need to delete the reference in § 131.123 and is proposing to make the change as set out below.

FDA is not proposing to revoke the standards of identity for nonfat dry milk and nonfat dry milk fortified with vitamins A and D, in §§ 131.125 and 131.127, respectively, because the use of the term ''nonfat'' in the names of these foods does not conflict with the definition of the term ''nonfat'' in § 101.62(b)(1). In addition, the agency notes that ''nonfat dry milk,'' as defined by the Nonfat Dry Milk, Milk Act of July 2, 1956, does not contain added vitamins A and D. Retention of these standards will minimize confusion as to whether these vitamins may be added to the food.

B. Vitamin Addition

The agency disagrees with the MIF's and CSPI's interpretation of the impact of revoking the standards of identity for lowfat and skim milk on the requirements for addition of vitamins A and D to lowfat milk or nonfat milk that conform to § 130.10. Under the existing standards for lowfat and skim milk products in part 131, vitamin A addition is mandatory, while vitamin D addition is optional. Vitamin A is required to be added to a level of 2,000 International Units (IU) per quart (500 IU or 10 percent of the DV per reference amount customarily consumed). When vitamin D is added, the level must be 400 IU per quart (100 IU or 25 percent of the DV per reference amount customarily consumed). However, under the general standard, the only requirement for lower-fat milk products is that they not be nutritionally inferior to milk as defined in § 131.110. Vitamin A levels in milk in winter have been reported to range from 500 to 1,000 IU per quart, while in summer (pasture), these levels range from 2,000 to 3,000 IU per quart (Ref. 2). Vitamin D levels range from 5 to 15 IU (Ref. 2). Because the removal of milkfat from milk in the production of the lower-fat milk products removes corresponding amounts of the naturally occurring fat soluble vitamins, some amount of these two vitamins would have to be added for the lower-fat products to comply with the general standard. However, under § 101.3(e), the amount required to be added is only that necessary to make the level in the lower-fat milk products at least equivalent to that in whole milk.

Because the addition of both vitamins A and D to whole milk is optional, the requirements for levels of 2,000 IU of vitamin A and 400 IU of vitamin D per quart would not apply to products under the general standard. Although such levels would be permitted, they would not be required. Addition of vitamins A and D to these levels would be permitted because milk under § 131.110 can contain these amounts and be named for example ''milk, vitamins A and D added.'' The lower-fat milks could have equivalent levels and be named for example ''reduced fat milk, vitamins A and D added,'' or ''nonfat milk, vitamin A added,'' as appropriate.

The same rationale applies to vitamin addition in the lower- fat yogurt products, in which both vitamin A and vitamin D addition is optional. There are no provisions for addition of vitamins to sweetened condensed skimmed milk. However, when the food is made under § 130.10, it must not be nutritionally inferior to sweetened condensed milk. Lower-fat evaporated milk products, however, must be fortified with vitamin D because addition of vitamin D in evaporated milk is mandatory.

The agency requests comment on whether current levels of vitamins A and D in the lower-fat milk products need to be maintained. Specifically, the agency requests information on levels of vitamins A and D currently in the milk supply and on the changes in these levels, if any, that are likely to occur if the standards of identity for the lowfat milk and skim milk products are

revoked. Information should include: (1) The percentage of milk currently optionally fortified with one or both vitamins and the likelihood of that changing; and (2) the percentage of lower-fat milk products currently so fortified, and the likelihood that the fortifications would continue if they were optional. Based on the information received in comments, FDA will consider whether special provisions are necessary (beyond the nutritional equivalency requirements of § 130.10) to require fortification of lowfat, reduced fat, and nonfat milk products manufactured under § 130.10.

C. Other Action—Unresolved Hearing Issue on the Lowfat Milk and Skim Milk Standards

In the Federal Register of October 6, 1983 (48 FR 45545), FDA published a notice of hearing on objections to a final rule (45 FR 81734, December 12, 1980) concerning the standards of identity for lowfat milk and skim milk (Docket Nos. 81N–204F and 76N–0175). The hearing was granted on four issues, three of which have been resolved (51 FR 40313, November 6, 1986). One issue dealing with labeling requirements of the standardized foods (i.e., the reasonableness of the decision to prohibit use of the terms ''protein fortified'' and ''fortified with protein'' on labels of lowfat milk and skim milk products containing not less than 10 percent milk-derived nonfat milk solids) has not been resolved. However, if a final rule is issued to remove the standards of identity for lowfat milk and skim milk in §§ 131.135 and 131.143, this unresolved issue will be rendered moot, and no further rulemaking procedures regarding the stayed provision will be necessary.

IV. Economic Impact

FDA has examined the economic implications of the proposed rule amending 21 CFR parts 101, 131, and 133 as required by Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches which maximize net benefits (including potential economic, environmental, public health and safety and other advantages; distributive impacts; and equity). The Regulatory Flexibility Act requires that the agency analyze options for regulatory relief for small businesses. FDA finds that this proposed rule is not a significant rule as defined by Executive Order 12866. In accordance with the Regulatory Flexibility Act, the agency certifies that the proposed rule will not have a significant impact on a substantial number of small businesses.

There are approximately 1,350 lowfat and 570 skim (nonfat) milk products currently on the market. These products correspond to approximately 3,500 lowfat milk and 1,600 nonfat milk stockkeeping units (SKU's). If this rule is finalized as proposed, all milk products currently using the terms ''lowfat'' and ''nonfat'' will have to comply with the definitions established for those claims. Any milk product not labeled in compliance with the term ''lowfat'' or ''nonfat'' will have to be relabeled. According to the petitioners, most products currently labeled as ''nonfat milk'' would be eligible to retain that name. However, many products currently labeled as ''lowfat milk'' will not be eligible to retain that name and will have to be relabeled as ''reduced fat milk''. Specifically, products containing more than 1 percent milkfat and currently labeled ''lowfat'' will have to be relabeled. There are approximately 750 such products and approximately 2,225 SKU's.

Potentially, this regulation will also require changes in the labeling of evaporated skimmed milk, lowfat dry milk, sour half-and-half, acidified sour half-and-half, lowfat and nonfat yogurts, and lowfat cottage cheese. There are approximately 5 evaporated skimmed milk products and 8 SKU's, 1 lowfat dry milk product and 4 SKU's, 12 sour half-and-half products and 16 SKU's, approximately 119 lowfat yogurts and 1,294 SKU's, approximately 91 nonfat yogurts and 813 SKU's, and approximately 142 lowfat cottage cheese products and 436 SKU's. There are no acidified sour half-and-half products in FDA's database. FDA estimates that almost none of the nonfat yogurts and lowfat cottage cheeses will require relabeling because these products most likely meet FDA's definitions for ''lowfat'' and ''nonfat''. However, the sour half-and-half products will require relabeling with the term ''reduced fat'' in conjunction with the term ''sour cream.'' FDA estimates that most of the lowfat yogurts contain too much fat to retain the term ''lowfat'' and will either be relabeled or reformulated.

There are four categories of costs associated with a mandatory relabeling: Administrative, analytical, redesign, and inventory disposal costs. The administrative costs associated with a labeling regulation are the dollar value of the incremental administrative effort expended in order to comply with a regulation. The magnitude of administrative costs to a representative firm is a function of several variables including the scope and intricacy of the regulation (positive relationship), the number of distinct products, and the length of the compliance period associated with the regulation (inverse relationship). This proposed regulation is not anticipated to be an intricate regulation. The administrative costs associated with a nonintricate regulation with a compliance period in excess of 1 year is $850 per small/medium firm and $6,300 per large firm. The total administrative costs associated with this proposed regulation are approximately $2.2 million.

Analytical tests are typically performed by technical personnel employed by firms or at independent laboratories. These costs consist of tests to determine nutrient and food component quantities required by various labeling provisions. The agency does not anticipate that this rule will cause any analytical testing. Because milk products are already subject to nutrition labeling requirements, firms should already be aware of the fat content of their products.

Incremental redesign costs depend on the type of printing process used, the complexity of the label change, and the length of the compliance period. Because printing activities are specific to individual labels, computing incremental printing effort on a per-SKU basis is necessary. The agency estimates that the changes required by this proposed regulation will result in a simple two-color label change. Also, because firms will have in excess of 1 year to comply, redesign costs will be reduced by the fact that they can incorporate mandated changes with previously planned label changes. Total redesign costs of the proposed regulation are estimated at $3 million.

An additional cost category is the label inventory loss associated with the transition from old to new labels. The cost of label inventory loss depends on average label inventory and the length of the compliance period. FDA is proposing an effective date that would allow for over 1 year for firms to comply with any final rule that may result from this rulemaking. A 1-year compliance period is sufficient to allow producers of milk, yogurt, sour half-and-half, and cottage cheese products to use up existing stocks of labels. Therefore, label inventory disposal costs will be zero. The agency estimates that the total costs of this proposed regulation will be approximately $5 million.

The agency believes that consumers will benefit from this regulation because it will provide consistency in the

nomenclature of both standardized and nonstandardized foods that bear nutrient content claims relating to their fat content.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(b)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Comments

Interested persons may, on or before January 23, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

1. Memorandum entitled ''Regulatory Reinvention Initiative'' from President Clinton to heads of departments and agencies, March 4, 1995.

2. Jenness, Robert and Patton, Stuart, *Principles of Dairy Chemistry*, John Wiley and Sons, Inc., NY, pp. 403–404, 1959.

List of Subjects

21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

21 CFR Part 131

Cream, Food grades and standards, Milk, Yogurt.

21 CFR Part 133

Cheese, Food grades and standards, Food labeling.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 101, 131, and 133 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packing and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.62 is amended by revising the introductory text of paragraph (b)(1) to read as follows:

§ 101.62 Nutrient content claims for fat, fatty acid, and cholesterol content of foods.

* * * * *

(b) ''*Fat content claims.*'' (1) The terms ''fat free,'' ''free of fat,'' ''no fat,'' ''zero fat,'' ''without fat,'' ''negligible source of fat,'' or ''dietarily insignificant source of fat'' or, in the case of milk products, ''skim'' may be used on the label or in labeling of foods, provided that:

* * * * *

PART 131—MILK AND CREAM

3. The authority citation for 21 CFR part 131 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 379e).

§ 131.122 [Removed]

4. Section 131.122 *Sweetened condensed skimmed milk* is removed from subpart B.

§ 131.123 [Removed]

5. Section 131.123 *Lowfat dry milk* is removed from subpart B.

§ 131.132 [Removed]

6. Section 131.132 *Evaporated skimmed milk* is removed from subpart B.

§ 131.135 [Removed]

7. Section 131.135 *Lowfat milk* is removed from subpart B.

§ 131.136 [Removed]

8. Section 131.136 *Acidified lowfat milk* is removed from subpart B.

§ 131.138 [Removed]

9. Section 131.138 *Cultured lowfat milk* is removed from subpart B.

§ 131.143 [Removed]

10. Section 131.143 *Skim milk* is removed from subpart B.

§ 131.144 [Removed]

11. Section 131.144 *Acidified skim milk* is removed from subpart B.

§ 131.146 [Removed]

12. Section 131.146 *Cultured skim milk* is removed from subpart B.

13. Section 131.149 is amended by revising the second sentence of paragraph (a) to read as follows:

§ 131.149 Dry cream.

(a) * * * Alternatively, dry cream may be obtained by blending dry milks as defined in §§ 131.125(a) and 131.147(a) with dry cream as appropriate, *Provided,* That the resulting product is equivalent in composition to that obtained by the method described in the first sentence of this paragraph. * * *

* * * * *

§ 131.185 [Removed]

14. Section 131.185 *Sour half-and-half* is removed from subpart B.

§ 131.187 [Removed]

15. Section 131.187 *Acidified sour half-and-half* is removed from subpart B.

§ 131.203 [Removed]

16. Section 131.203 *Lowfat yogurt* is removed from subpart B.

§ 131.206 [Removed]

17. Section 131.206 *Nonfat yogurt* is removed from subpart B.

PART 133—CHEESES AND RELATED CHEESE PRODUCTS

18. The authority citation for 21 CFR part 133 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 379e).

§ 133.131 [Removed]

19. Section 133.131 *Lowfat cottage cheese* is removed from subpart B.

Dated: October 27, 1995.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 95–27712 Filed 11–8–95; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 902

[SPATS AK–004–FOR; Alaska Amendment IV]

Alaska Regulatory Program

ACTION: Proposed rule; reopening and extension of public comment period on proposed amendment.

SUMMARY: OSM is announcing receipt of revisions and additional explanatory information pertaining to a previously proposed amendment to the Alaska regulatory program (hereinafter, the ''Alaska program'' under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The revisions and additional explanatory information for Alaska's proposed rules pertain to permit fees, geology description, return of excess spoil to underground